K103520

JUN 24 2011

Edwards

510(k) Summary

Submitter:	Edwards Lifesciences LLC
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Date Prepared:	June 15, 2011
Trade Name:	Carpentier-Edwards® Physio Tricuspid™ annuloplasty ring, model 6200
Classification Name:	Class II, CFR 870.3800 Annuloplasty Ring, KRH
Predicate Device(s):	Edwards MC3® Tricuspid annuloplasty ring (K020864) Cosgrove-Edwards® annuloplasty system (K923367) Carpentier-Edwards® Classic® Tricuspid annuloplasty ring (K912554)
Device Description:	The Carpentier-Edwards Physio Tricuspid annuloplasty ring, model 6200, is constructed of a titanium core with a silicone sewing ring margin covered with a polyester cloth.
Indications for Use:	The Carpentier-Edwards Physio Tricuspid annuloplasty ring, model 6200, is intended for use in patients with tricuspid valvular insufficiency. It is intended to correct annular dilatation, increase leaflet coaptation, reinforce annular suture lines, and prevent further dilatation of the annulus.
Comparative Analysis:	It has been demonstrated that the Carpentier-Edwards Physio Tricuspid annuloplasty ring, model 6200, is comparable to its predicate devices in design, intended use, materials, fundamental technology and principal of operation.
Functional/Safety Testing:	The Carpentier-Edwards Physio Tricuspid annuloplasty ring, model 6200, has successfully completed design verification and validation testing. The following studies were conducted: • Computational stress analysis • Finite element analysis

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- Tensile strength
- Suture retention
- Flexibility
- Ring / Ring holder removal force
- Corrosion resistance
- Magnetic resonance compatibility (RF heating, image artifact, displacement force, induced torque)
- Biocompatibility (percent inhibition of cell growth, medium eluate method – cytotoxicity, blood compatibility, complement activation, gene mutation assay, chromosomal aberration effect assay, agar overlay – cytotoxicity, DNA damage / effects assay, Mouse systemic injection – systemic toxicity, rabbit pyrogen – systemic toxicity, rabbit intracutaneous reactivity, guinea pig maximization, rabbit intramuscular implantation – sub-chronic and chronic evaluations)
- Relative resistance evaluation and comparison for sterilization
- Bioburden
- Limulus amebocyte lysate pyrogen testing
- Packaging qualification (visual inspection, sterile barrier integrity, dye leak, burst)
- Shelf-life assessments of packaging and product components
- Design validation by surgeons in simulated use environment

Standards used in support of the application	See the attached table
Conclusion:	The Carpentier-Edwards Physio Tricuspid annuloplasty ring, model 6200, is substantially equivalent to its predicate devices.

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Utilization of Standards

Standard No.	Standard Title
ISO 10993-1:2009	Biological evaluation of medical device – Part 1: Biological Testing
ASTM F2182:2009	Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging
ASTM F2052:2006	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2119:2007	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
ASTM F2213:2006	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
BS EN ISO 11607-1:2009	Packaging for Terminally Sterilized Medical Devices, Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems (ISO 11607-1:2006)
ASTM D4169:2005	Standard Practice for Performance Testing of Shipping Containers and Systems
ISO 14971:2007	Medical Devices - Application of risk management to medical devices

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 24 2011

Edwards Lifesciences, LLC
c/o Mr. Daryl Richardson
Regulatory Affairs Associate
One Edwards Way
Irvine, CA 92614

Re: K103520
Carpentier-Edwards™ Physio Tricuspid™ Annuloplasty Ring, Model 6200
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty ring
Regulatory Class: Class II
Product Code: KRH
Dated: June 22, 2011
Received: June 23, 2011

Dear Mr. Richardson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103520

Device Name: Carpentier-Edwards Physio Tricuspid annuloplasty ring, model 6200

Indications for Use:

The Carpentier-Edwards Physio Tricuspid annuloplasty ring, model 6200, is intended for use in patients with tricuspid valvular insufficiency. It is intended to correct annular dilatation, increase leaflet coaptation, reinforce annular suture lines, and prevent further dilatation of the annulus.

Prescription Use: ☒ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: ☐ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K103520